

Remarks/Arguments:

As a preliminary matter, it is noted with appreciation that the Examiner has acknowledged the claim for domestic priority under 35 U.S.C. § 120. The Examiner's acknowledgement of Applicants' claim for foreign priority under 35 U.S.C. § 119 is respectfully requested. The claim for priority was made in the Declaration papers filed with this application.

Regarding the Examiner's statement regarding priority in Paragraph 3 of the Office Action, an appropriate amendment has been made to the specification to include a statement listing all continuing data following the title of the invention, including the current status of all non-provisional parent applications.

Regarding Paragraphs 4 and 5 of the Office Action (double patenting), an appropriate Terminal Disclaimer is intended to be filed in due course to overcome the rejection of the identified claims of this application based on the identified claims of U.S. Patent No. 5,800,508.

Claim Rejections -- 35 U.S.C. § 112

Regarding Paragraphs 6 and 7 of the Office Action, which set forth a rejection of claim 33 under 35 U.S.C. § 112, first paragraph, the Examiner's attention is directed to the following support for the subject matter of claim 33 found in the specification as originally filed. Specifically, the Examiner's attention is directed to original claim 33 at page 63 of the specification as filed. The Examiner's attention is also directed to the originally filed specification at page 10, lines 20-25. Based on at least those disclosures in the original specification, there is clear support under 35 U.S.C. § 112, first paragraph, for the suture being a tied loop of thermoplastic material, as recited in claim 33. Accordingly, withdrawal of the rejection of claim 33 under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Regarding Paragraphs 8 and 9 of the Office Action, which set forth a rejection of claim 29 under 35 U.S.C. § 112, second paragraph, claim 29 has been amended to clarify the "an additional stent segment" language. Accordingly, withdrawal of the rejection of claim 29 under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Claim Objections

Regarding the claim objections set forth in Paragraph 10 of the Office Action, appropriate non-narrowing amendments have been made in order to clarify the language objected to by the Examiner. Specifically, claim 20 has been amended to clarify "additional stent segments"; claim 39 has been amended to recite "substantially perpendicular" as opposed to "square"; and claims 54, 55, and 56 have been amended to recite a "longitudinal axis" to clarify the term "axis." For the foregoing reasons, withdrawal of the objections to claims 20, 22-25, 27-30, 39, 54-56 is respectfully requested.

Claim Rejections -- 35 U.S.C. § 102

Claims 20, 22-24, 31-33, 41, 54, and 55 stand rejected under 35 U.S.C. § 102(e) as anticipated by Cragg (U.S. Patent No. 5,405,377).

Independent claim 54 recites that "each of said hoops [are] oriented in a plane substantially perpendicular to the longitudinal axis of the stent." See, for example, the specification at page 9, lines 13-19, which recites that, as an alternative to the wire having a helical configuration, the wire may be of an entirely novel configuration, namely one in which the wire forms a plurality of hoops such that the plane of the circumference of each hoop is substantially perpendicular to the longitudinal axis of the stent.

The Office Action cites Figures 1-4 and column 2, line 40, through column 3, line 4, of Cragg. The cited portions of Cragg fail, however, to disclose hoops oriented in a plane substantially perpendicular to the longitudinal axis of the stent.

For the foregoing reasons, Cragg fails to anticipate claim 54 or claims 20, 22-24, 31-33, 41, or 55, each of which is directly or indirectly dependent upon claim 54. Accordingly, withdrawal of the rejection based on Cragg is respectfully requested.

Claims 20, 22-24, 31, 54-57 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Fontaine (U.S. Patent No. 5,370,683).

Claim 54 recites that "each of said hoops [are] oriented in a plane substantially perpendicular to the longitudinal axis of the stent" as mentioned previously in connection with

the discussion of the Cragg reference. Similarly, claim 56 recites that "the vertices of each hoop . . . lie in a common plane perpendicular to the axis of the tubular member."

The Office Action cites Figures 6, 9, 10, and 14 as well as lines 42-56 of column 4 of Fontaine. Fontaine fails, however, to disclose that each of the hoops is oriented in a plane substantially perpendicular to the longitudinal axis of the stent (as recited in claim 54) or that the vertices of each hoop lie in a common plane perpendicular to the axis of the tubular member (as recited in claim 56). In fact, the disclosure in Fontaine cited in the Office Action is strictly limited to wave forms "a", "b" and "c" in Figure 6 of Fontaine. Elsewhere, Fontaine further explains that the expanded wave form of Figure 3 is formed into a stent by wrapping it, *in a spiral*, around a mandril. See Fontaine at Column 4, lines 13-15, for example.

For the foregoing reasons, the Fontaine reference fails to anticipate independent claims 54 and 56 as well as claims 20, 22-24, 31, 55, and 57, which are directly or indirectly dependent upon independent claims 54 and 56. Accordingly, withdrawal of the rejection based on Fontaine is respectfully requested.

Claims 20, 22-25, 31, 32, 39, 54-55 stand rejected under 35 U.S.C. § 102(e) as anticipated by Maeda (U.S. Patent No. 5,800,456).

As discussed previously, claim 54 recites that each of the hoops is oriented in a plane substantially perpendicular to the longitudinal axis of the stent.

The Office Action cites lines 42-56 of column 4, but that disclosure of Maeda fails to suggest a stent in which each hoop is oriented in a plane substantially perpendicular to the longitudinal axis of the stent. In fact, the passage cited in the Office Action teaches the opposite; namely, that a helical pattern (shown in the figures of Maeda) allows the elongated stent to more uniformly accommodate curves in the vascular system of a patient, that the helical structure produces a more uniform radial expansile force along the length of the stent, and that the spiral stents of the Maeda invention are more reliable in maintaining their position within a patient. See Maeda at column 4, lines 42-48, for example.

The Office Action also cites Figure 8 as showing the longitudinal ends of the stent being square to the long axis of the stent. There is no disclosure, however, in Maeda for a stent in which each of the hoops is oriented in a plane substantially perpendicular to the longitudinal axis of the stent.

For the foregoing reasons, Maeda fails to anticipate claim 54 or claims 20, 22-25, 31, 32, 39, and 55, each of which is directly or indirectly dependent upon claim 54. Accordingly, withdrawal of the rejection based on Maeda is respectfully requested.

Claims 20, 22-25, 39, 43, 44, 47 and 54-55 stand rejected under 35 U.S.C. § 102(b) as anticipated by Wolff (U.S. Patent No. 5,104,404).

Claim 55 recites "means for securing an apex of one hoop to a juxtaposed apex of a neighboring hoop." For illustration purposes, the securing means can be used for securing an apex of the sinuous wire in one hoop to a juxtaposed apex of a neighboring hoop so that each hoop is supported by its neighbors; for example, the securing means may comprise a loop element of a suture material to tie the juxtaposed apices together. See page 10, lines 16-23, of this application, for example.

Wolff relates particularly to arteries which have a curved portion, curved and recurved portions, changes in diameter, which are difficult to obtain using existing stents. See column 1, lines 14-19 of Wolff. Accordingly, Wolff discloses a device that utilizes a number of stent segments flexibly connected together by a hinge between each adjacent stent segment. See Wolff at column 1, lines 45-47. This approach, according to Wolff, permits articulation between adjacent stent segments and also maintains the spacing between adjacent segments as established by the hinge lengths. See Wolff at column 1, lines 47-52, for example. The spacing between stent segments is also shown by Wolff in Figs. 1, 3, 4 and 6.

The Office Action fails to identify any disclosure in Wolff of such a means for securing an apex of one hoop to a *juxtaposed* apex of a neighboring hoop. Specifically, Wolff fails to disclose means for securing an apex of one hoop to a *juxtaposed* apex of a neighboring hoop.

For the foregoing reasons, Wolff fails to anticipate claim 54 and claims 20, 22-25, 39, 43, 44, 47, and 55, each of which is directly or indirectly dependent upon claim 54. Accordingly, the withdrawal of the rejection based on Wolff is respectfully requested.

Claim Rejections -- 35 U.S.C. § 103

Claims 45, 46, 48, and 49 stand rejected as being unpatentable based on a proposed combination of Wolff with Piplani (U.S. Patent No. 5,824,039).

It is respectfully submitted that the proposed combination of Wolff with Piplani, even if such a combination were suggested, fails to establish *prima facie* obviousness. Specifically, even the proposed combination of Wolff and Piplani fails to disclose or suggest means for securing an apex of one hoop to a *juxtaposed* apex of a neighboring hoop. As discussed previously, Wolff fails to disclose or suggest this feature recited in claim 54 (upon which each of claims 45, 46, 48, and 49 is dependent). Piplani fails to compensate for the deficiency of Wolff, so the hypothetical combination itself is inadequate to establish *prima facie* obviousness.

Additionally, none of the passages of Wolff and Piplani cited in the Office Action suggests a radiopaque element attached to one end of a stent (claim 44, upon which claims 45 and 46 depend) or a radiopaque tube disposed around a part of a stent (claim 47, upon which claims 48 and 49 depend). Instead, the first cited passage of Piplani (applied in the Office Action to show markers) describes a graft body in which markers are "secured to the fabric of the graft by suitable means such as Dacron sutures." Column 5, lines 21-25 of Piplani. The second passage from Piplani cited in the Office Action relates to markers on the tubular member 188 within a balloon catheter. For these additional reasons, a *prima facie* case of obviousness has not been established.

Even if the proposed combination of references taught each element of the rejected claims (as it must to establish *prima facie* obviousness), there is no suggestion to combine Wolff with Piplani in the manner suggested in the Office Action and to further modify the combination in such a way as to arrive at applicants' claimed invention. The U.S. Court of Appeals for the Federal Circuit has stated that "[t]he mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." *In re Fritch*, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992) (citing *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984)).

For the foregoing reasons, withdrawal of the rejection of claims 45, 46, 48, and 49 based on the proposed combination of Wolff and Piplani is respectfully requested.

Conclusion

In view of the foregoing amendments and remarks, it is respectfully submitted that this application is now in proper form for allowance. A Notice of Allowance is therefore respectfully requested.

Respectfully submitted,

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